US 20050159738A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2005/0159738 A1

Visram et al. (43) Pub. Date: Jul. 21, 2005

(54) SURGICAL PERFORATION DEVICE WITH ELECTROCARDIOGRAM (ECG) MONITORING ABILITY AND METHOD OF USING ECG TO POSITION A SURGICAL PERFORATION DEVICE

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(21) Appl. No.: 10/760,479

(22) Filed: Jan. 21, 2004

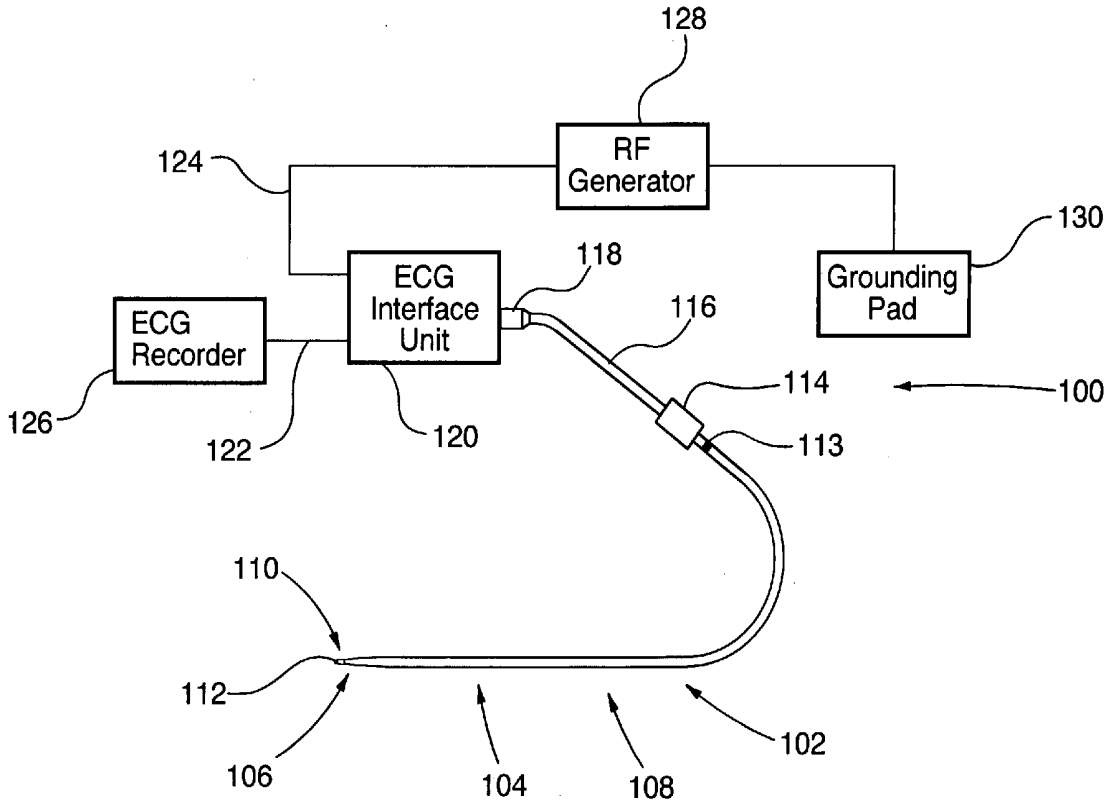
Publication Classification

(51) Int. Cl.[7] A61B 18/18

(52) U.S. Cl. 606/34; 606/41; 606/45

(57) ABSTRACT

A device with a functional tip containing at least one active electrode capable of creating a controlled perforation in body tissue through the application of energy (e.g. Radio Frequency (RF)) is described. The position of the tip of the device can be determined in response to ECG measured at the tip and determined by a monitor coupled to the device. The device is useful to remove or perforate unwanted tissue in a controlled manner in any location in the body, particularly in the atrial septum for controlled transseptal puncture. In this application, the device is introduced into the right atrium, and the functional tip is then positioned against the atrial septum. ECG is used to locate the region of the fossa ovalis on the atrial septum. Energy is applied to create the perforation and ECG is monitored to determine if the perforation was created in a desired location.



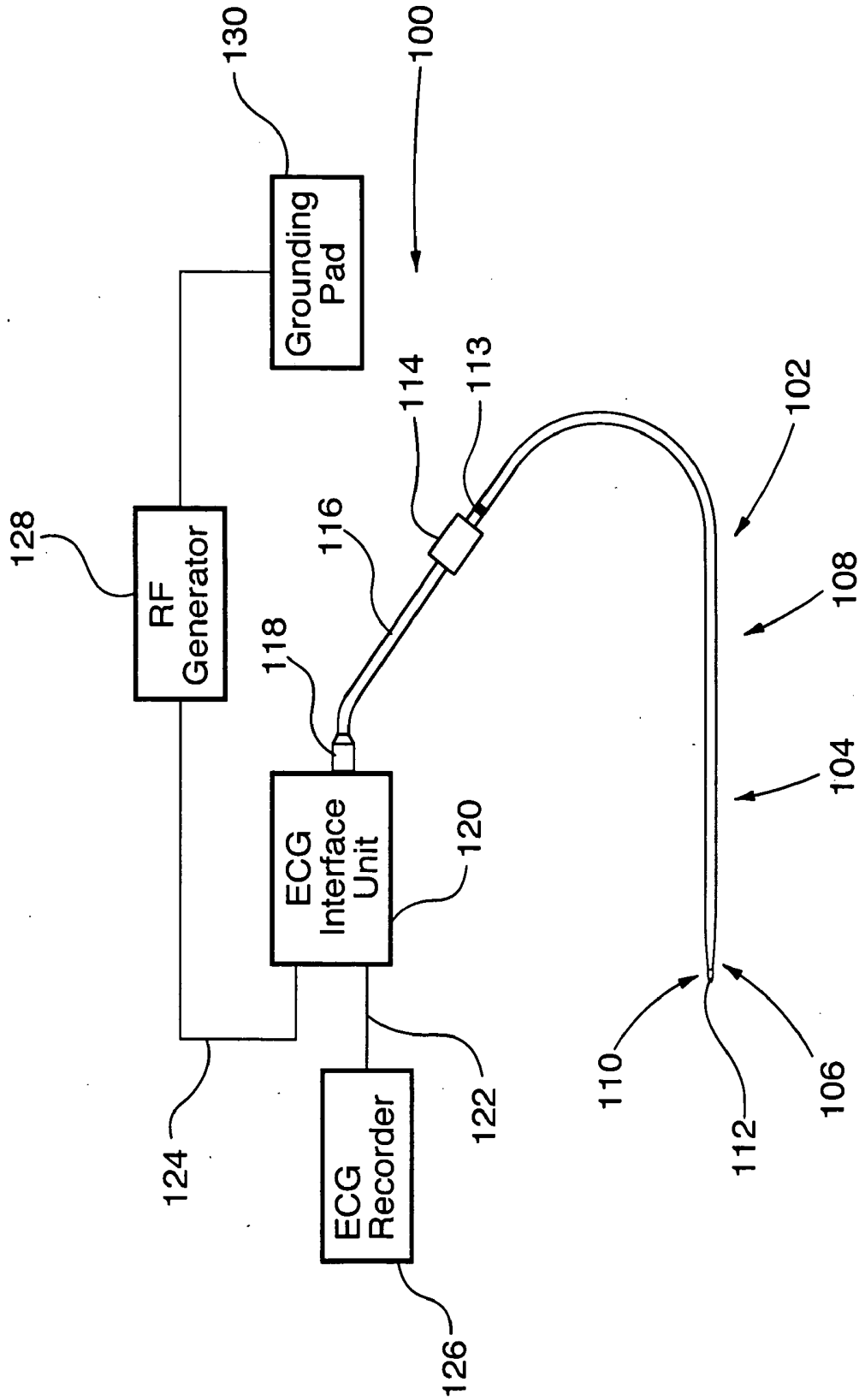

130
100
Grounding Pad
114
113
102
128
RF Generator
116
108
118
104
ECG Interface Unit
120
110
106
112
122
124
ECG Recorder
126

FIG.1

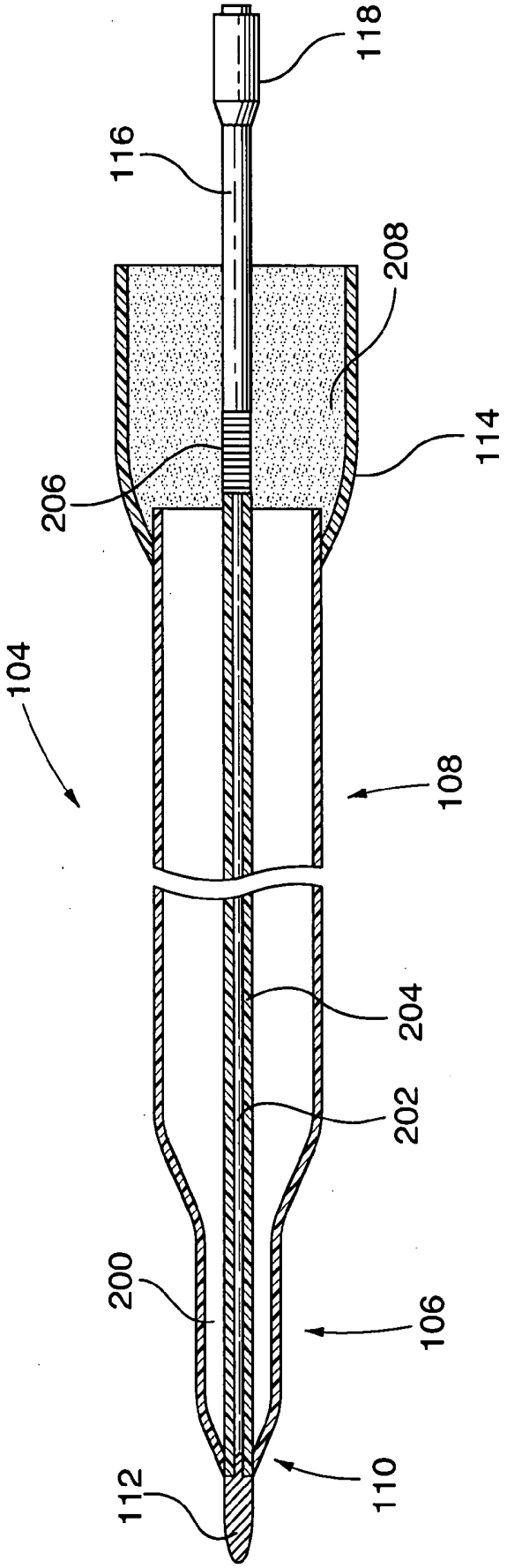


FIG.2

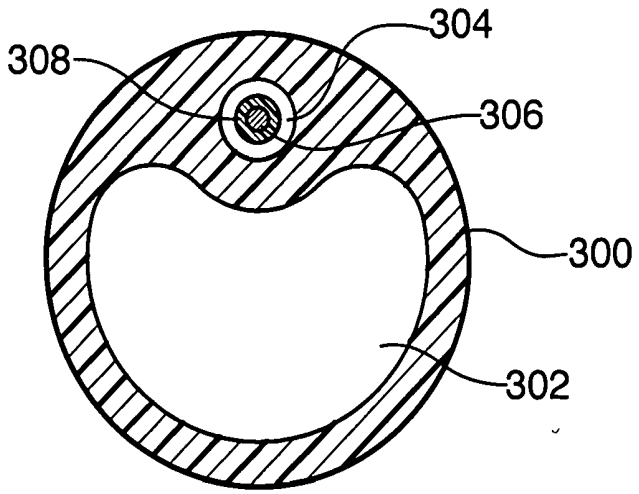


FIG.3

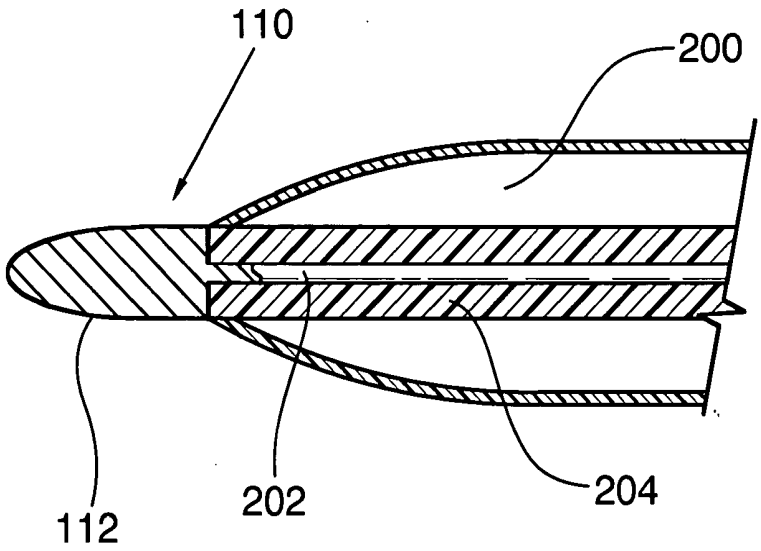


FIG.4

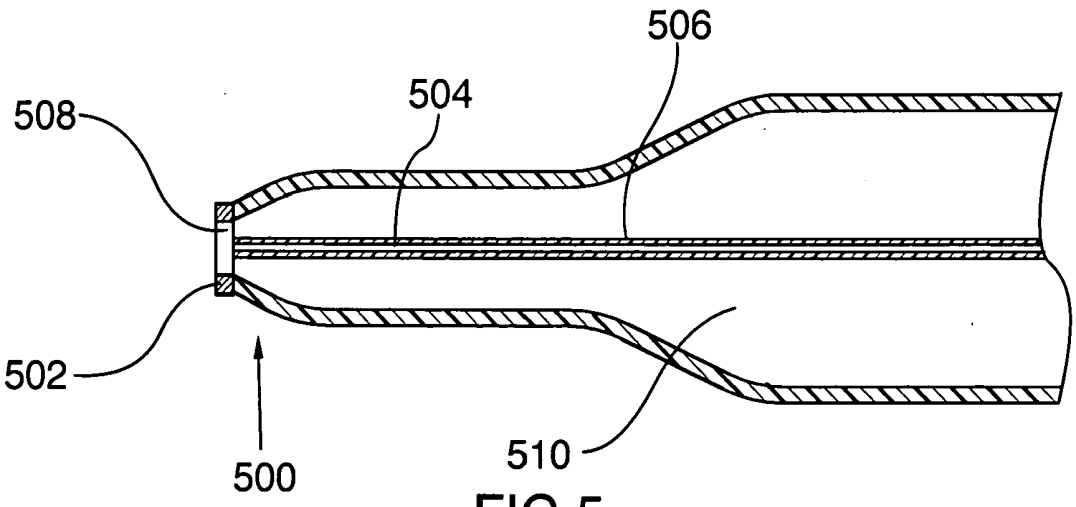


FIG.5

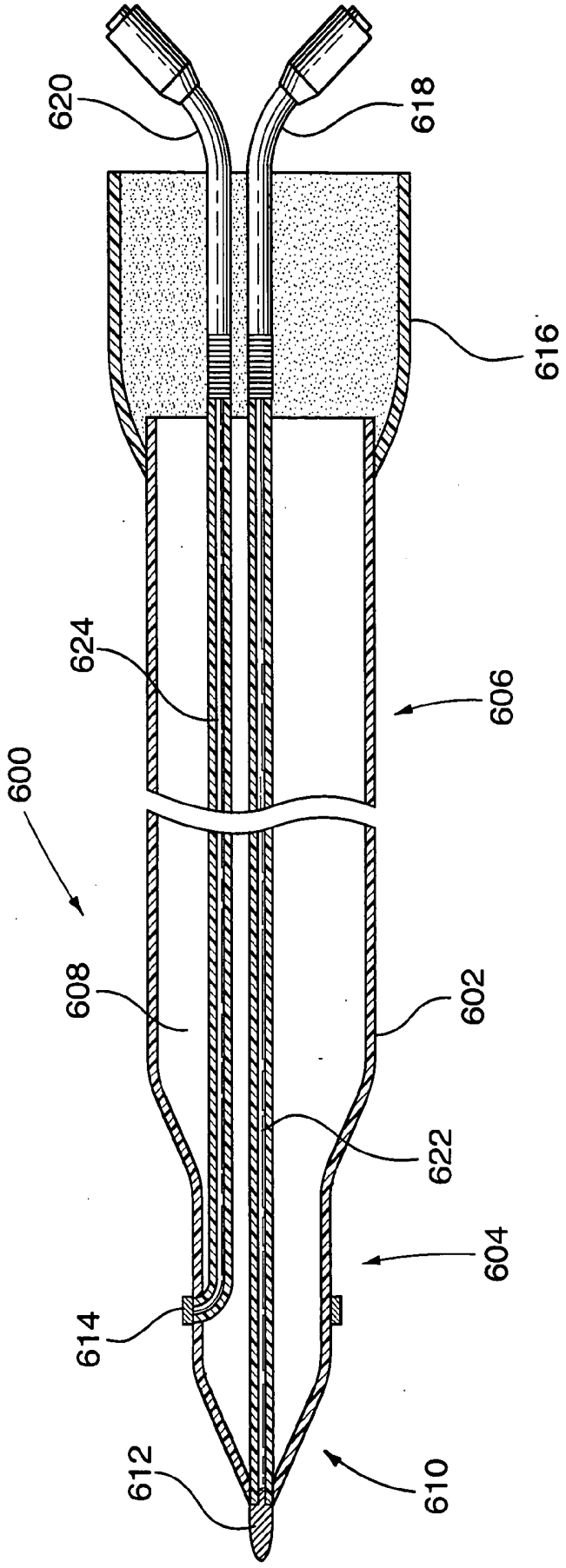


FIG.6

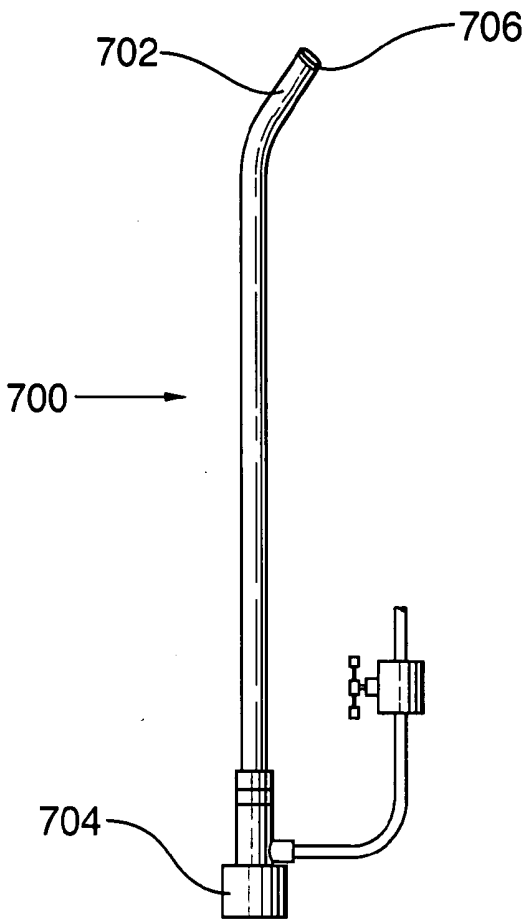


FIG.7A

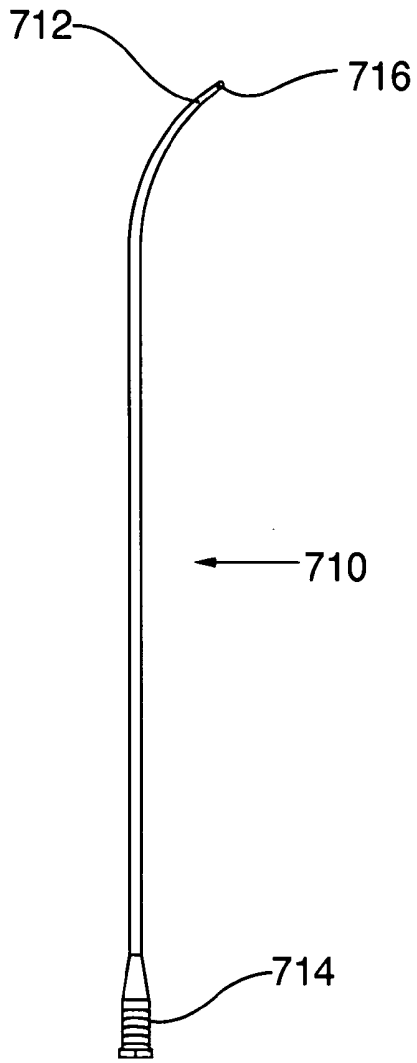


FIG.7B

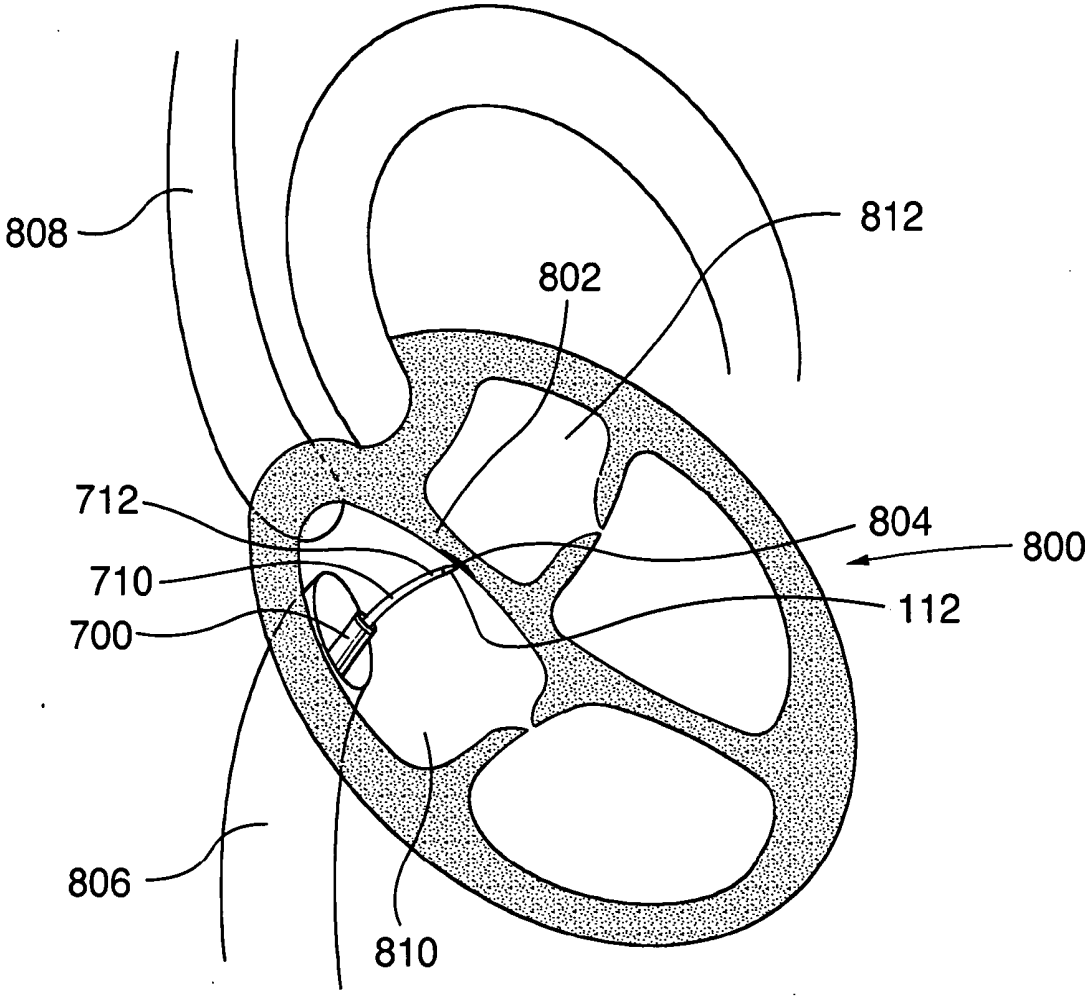


FIG.8

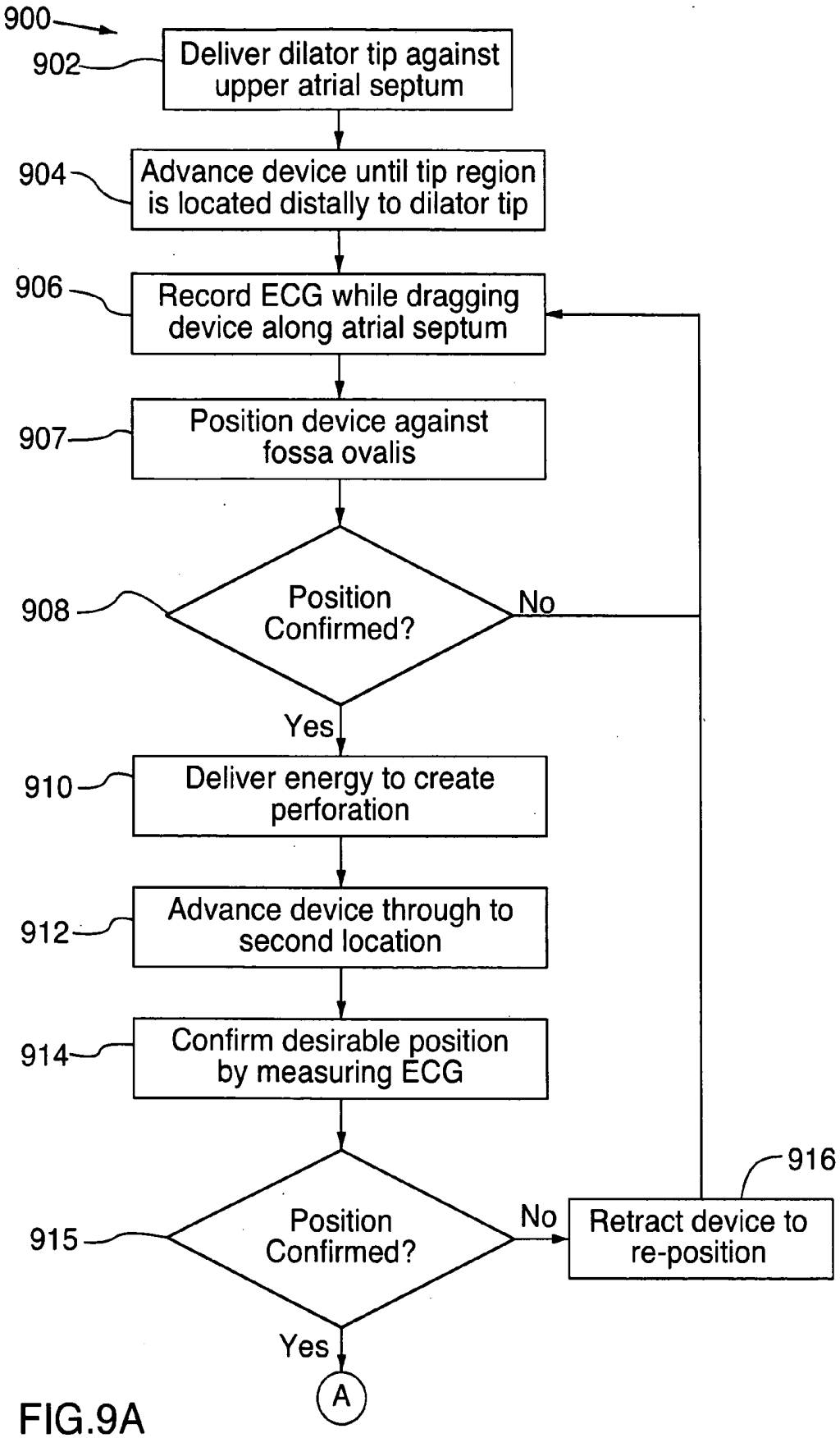

900
902
Deliver dilator tip against upper atrial septum
904
Advance device until tip region is located distally to dilator tip
906
Record ECG while dragging device along atrial septum
907
Position device against fossa ovalis
908
Position Confirmed?
No
Yes
910
Deliver energy to create perforation
912
Advance device through to second location
914
Confirm desirable position by measuring ECG
915
Position Confirmed?
No
916
Retract device to re-position
Yes
A

FIG.9A

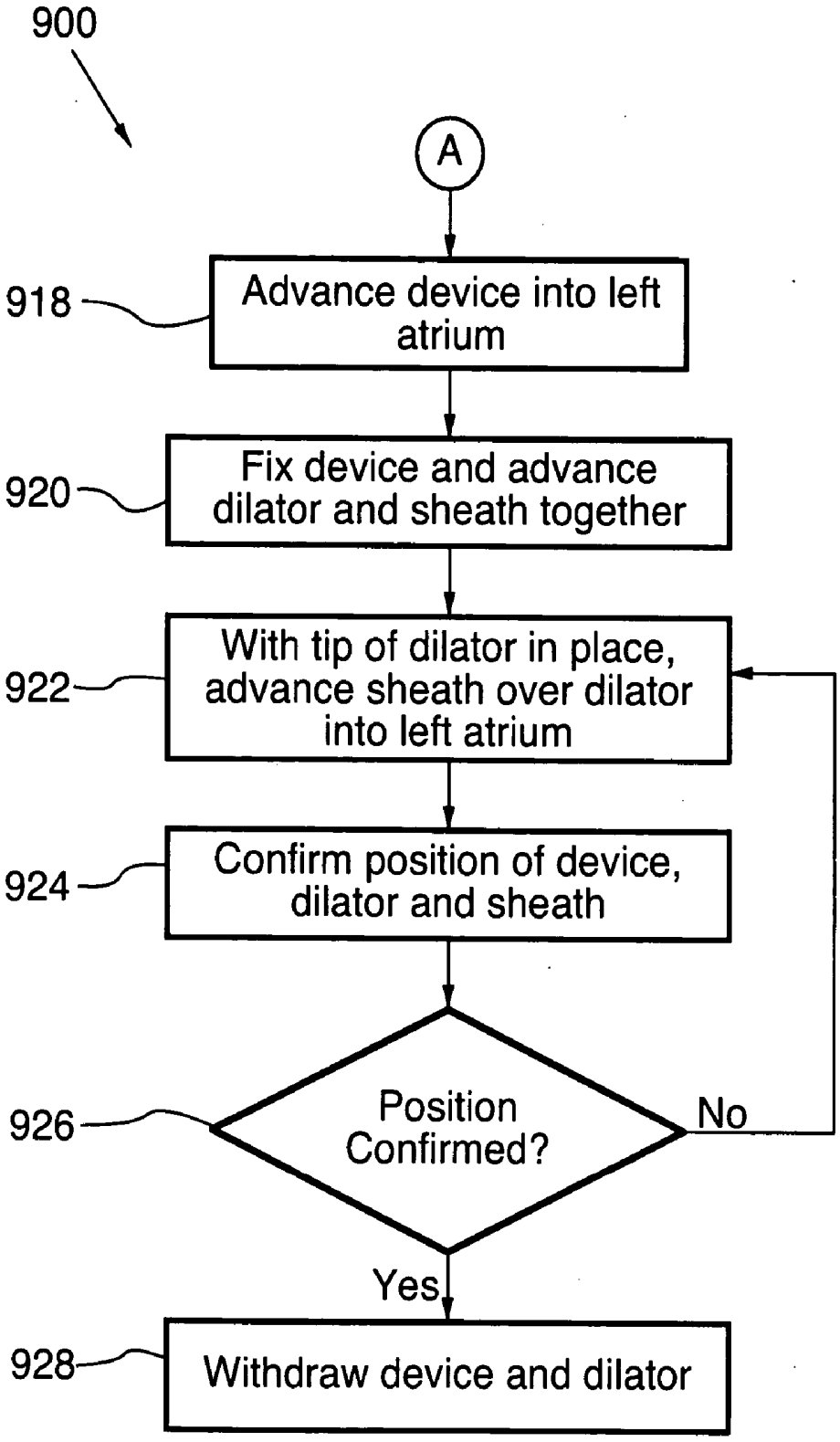

900
A
918
Advance device into left atrium
920
Fix device and advance dilator and sheath together
922
With tip of dilator in place, advance sheath over dilator into left atrium
924
Confirm position of device, dilator and sheath
926
Position Confirmed?
No
Yes
928
Withdraw device and dilator

FIG.9B

SURGICAL PERFORATION DEVICE WITH ELECTROCARDIOGRAM (ECG) MONITORING ABILITY AND METHOD OF USING ECG TO POSITION A SURGICAL PERFORATION DEVICE

TECHNICAL FIELD

[0001] The invention relates to a surgical perforation device with ECG monitoring ability and method of using ECG to position the surgical device. More specifically, the invention relates to a device and method for creating a controlled perforation in the atrial septum while using ECG to locate the fossa ovalis region on the atrial septum, and delivering a dilator and guiding sheath to the left atrium through the perforation over the surgical device.

BACKGROUND OF THE ART

[0002] Electrosurgical devices perforate or cut tissues when radio frequency (RF) electrical energy rapidly increases tissue temperature to the extent that the intracellular fluid becomes converted to steam, inducing cell lysis as a result of elevated pressure within the cell. The radio frequency range lies between 10 kHz and 300 MHz, but electrosurgical devices usually operate at a frequency between 400 kHz and 550 kHz. This technology can be used to create perforations in different types of tissue, such as heart tissue, vascular occlusions, and others. Commonly, RF devices are described for use in perforating vascular occlusions. A device to dilate and/or lance blood vessels that are morbidly contracted or clogged is described in a European Patent Application of Osypka, Publication Number EP 0315730, published May 15, 1989. This device describes the use of RF energy in either bipolar or monopolar application modes to open blood vessels by means of heat. Other devices intended to use RF energy to pass through occluded vessels have also been described (U.S. Pat. No. 5,364,393, of Auth et al., issued Nov. 15, 1994, WO 93/20747, publication of PCT Patent Application No. PCT/US93/03759, of Rosar, published Oct. 28, 1993, U.S. Pat. No. 5,098,431, of Rydell, issued Mar. 24, 1992, and U.S. Pat. No. 4,682,596 of Bales et al., issued Jul. 28, 1987). U.S. Pat. No. 6,293,945 B1, of Parins et al., issued Sep. 25, 2001 describes an electrosurgical instrument with suction capability. This device has three functions at the tip including cutting, coagulating, and suction. None of these devices however incorporate a means for verifying the location of the device within the body. One means for verifying location is described in U.S. Pat. No. 4,936,281, of Stasz, issued Jun. 26, 1990, which describes an ultrasonically enhanced RF catheter used for cutting. An ultrasonic transducer connected to an electronics module receives echo signals, enabling Doppler flow readings and ultrasound imaging of the vessel.

[0003] Having reliable information about the location of electrosurgical devices within a heart is an important aid to performing a successful procedure. It is often valuable to have more than one source of this information because every imaging technique has limitations, and using only one method can lead to erroneous information. A number of different tools and techniques have been used to assist the physician in locating devices within a heart. These include the use of fluoroscopy, cardiac pressure monitoring, transesophageal echocardiography, intracardiac echocardiography and the use of other devices in the heart to identify certain landmarks. L. J Jordaens et al. (2001) states that intracardiac echocardiography provides potentially useful information for electrophysiological studies and pacemaker implantation by visualization of important anatomical landmarks and structures.

[0004] Monitoring the ECG tracings from an intracardiac surgical device can be a useful tool to verify the position of the device in a heart. An electrode with reference to a ground or a pair of electrodes placed directly on or in the heart will record a repeating pattern of changes in electrical action potential. Action potential can be defined as an explosion of electrical activity that is created by a depolarizing current within biological cells. As action potentials spread from the top chambers of the heart (atria) to the bottom chambers of the heart (ventricles), the voltage measure between a single electrode and a ground or a pair of electrodes will vary in a way that provides a picture or electrocardiogram of the electrical activity of the heart. The nature of this picture can be varied by changing the position of the recording electrode(s); different locations in the heart are known to have characteristic ECG tracings or measurements. A bipolar recording is the voltage measurement between two electrodes and a unipolar recording is the voltage measurement between a single electrode and an electrode that is attached to a patient or an electrode that is built into a recorder or electrocardiograph and maintained at zero potential (ground). J. A. Alvarez et al. (1991) who conducted experiments where ECG signals were monitored in a heart using a transseptal needle states that the endoatrial electrocardiogram registered while the needle (Brockenbrough transseptal needle) pressed muscular areas of the septum or the free atrial wall showed marked injury curves; on the other hand, no significant changes (in the endoatrial electrocardiogram) were observed at the area assumed to be the fossa ovalis floor. This implies that the ECG tracing observed when a surgical device is in contact with the fossa ovalis which is a membranous region will be markedly different from ECG tracing observed on the muscular areas of the atrial septum or the free atrial wall. This difference in the electrocardiogram may be used to locate a surgical device on the region of the fossa ovalis in a heart.

[0005] Knowing the electrical action potential or ECG at the tip of a perforation device is a useful tool to determine the location of the device, particularly in instances where imaging techniques provide inconclusive information. A device that is used for monitoring and recording the electrical activity of the heart is described in U.S. Pat. No. 4,892,104, of Ito et al., issued Jan. 9, 1990; however the device is not capable of perforating tissue using RF energy. U.S. Pat. No. 6,296,615 B1, of Brockway et al., issued Oct. 2, 2001, describes a catheter with a physiological sensor. This catheter consists of a pressure transducer for monitoring pressure, as well as the ability to detect and/or transmit an electrical signal.

[0006] It is often required to create a perforation in the atrial septum to gain access to the left side of the heart interventionally to study or treat electrical or morphological abnormalities. It is also often desirable to create a hole in the septum in order to shunt the blood flow between the left and right sides of the heart to relieve high pressure or provide more blood flow to certain areas. The location on the atrial septum where a perforation is most commonly created is the fossa ovalis. The fossa ovalis is an oval depression in the inferior part of the interatrial septum. It represents the

foramen ovale of the fetus and is generally a thin membraneous structure. Since the atrial septum is muscular in nature, it is generally easier to create a perforation across the fossa ovalis to gain access to the left side of a heart. Historically in these instances, a dilator and guiding sheath are introduced into the femoral vein over a guidewire and advanced into the right atrium. The guidewire, dilator and guiding sheath are usually packaged as a kit with the guiding sheath designed to track over the dilator. In most designs, the distal end of the dilator extends out beyond the distal end of the sheath once the two devices are locked together. Once the dilator and guiding sheath are positioned appropriately in the right atrium, a stiff needle such as the Transseptal needle of Cook Incorporated, Bloomington, Ind., USA is introduced through the dilator and guiding sheath set in the femoral vein and advanced through the vasculature into the right atrium. From there the needle tip is positioned at the fossa ovalis, the preferred location on the septum for creating a hole. Once in position, mechanical energy is used to advance the needle through the septum and into the left atrium. Once in the left atrium the needle can be attached to a pressure transducer and the operator can confirm a left atrial pressure before continuing with the procedure. An operator may dilate the hole by advancing the dilator over the needle into the left atrium and tracking the guiding sheath over the dilator and into the left atrium to provide access for other devices to the left heart once the needle and dilator are removed. As well, the operator may use another device such as a balloon catheter delivered over a guidewire to enlarge the hole made by the needle if a shunt between the right and left atria is desired.

[0007] Another device and method for creating a transseptal puncture is described in U.S. Pat. No. 5,403,338, of Milo, issued Apr. 4, 1995, which describes a punch that is intended to create an opening between two compartments. This device also makes use of mechanical energy, as with the transseptal needle.

[0008] These methods of creating a transseptal perforation rely on the skill of the operator and require practice to be performed successfully. The needles used in this procedure are very stiff and can damage the vessel walls as they are being advanced. In addition, the amount of force required to perforate the septum varies with each patient. If too much force is applied there is the possibility of perforating the septum and continuing to advance the needle so far that damage is done to other areas of the heart. C. R. Conti (1993) discusses this possibility, and states that if the operator is not careful, the posterior wall of the heart can be punctured by the needle when it crosses the atrial septum because of the proximity of the two structures. It can also be difficult to position the needle appropriately in hearts that have malformations, or an atypical orientation. Justino et al. (2001) note that despite improvements to the technique with the needle since its first introduction, most large studies continue to report failed or complicated mechanical transseptal punctures, for reasons such as unusual septal thickness, or contour. Patients with a muscular septum, as well as those with a thick septum can benefit from an alternative to the transseptal needle puncture (Benson et al, 2002), as it is difficult to control the amount of mechanical force required to create the puncture. Furthermore, children born with heart defects such as hypoplastic left heart syndrome could benefit from an alternative technique. The abnormal anatomy of these patients including a small left atrium increases the likelihood of injury or laceration of surrounding structures during transseptal puncture (Sarvaas, 2002). The patient population discussed above would benefit from a device and technique for transseptal perforation that allows for a more controlled method of perforation and a method to confirm that the perforation has been made in the correct location.

SUMMARY OF THE INVENTION

[0009] The present invention provides a surgical perforation device with ECG monitoring ability and method of using ECG to position the surgical device.

[0010] In accordance with a first aspect of the invention, there is provided a surgical device for cutting material and ECG monitoring ability. The surgical device comprises an elongate member having a distal region and a proximal region; an energy delivery device associated with the elongate member at the distal region for delivering cutting energy to the material, said energy delivery device adapted for connection to an energy source; and an ECG monitoring mechanism associated with the distal region for monitoring ECG about the distal region.

[0011] The cutting energy is at least one form of energy selected from a group consisting of: electrical current; microwave; ultrasound; and laser. When the energy is electrical current, the current may have a frequency within the radio frequency (RF) range. Further, when the material to be cut comprises cellular tissue, the energy delivery device is operable to deliver sufficient energy to the tissue to result in a rapid increase in the intracellular temperature causing vaporization of intracellular water and subsequent cell lysis.

[0012] In accordance with an embodiment of the first aspect, the ECG monitoring mechanism comprises at least one active electrode about the distal region; said ECG monitoring mechanism is adapted for connection to an ECG recorder such as an electrocardiograph. The ECG monitoring mechanism may be configured for operation in accordance with one or more of a unipolar mode and a bipolar mode. For example, a zero potential or ground electrode may be provided by an electrocardiograph coupled to the ECG monitoring mechanism to provide unipolar ECG recording. In accordance with another embodiment of the first aspect, the ECG monitoring mechanism may comprise two electrodes about the distal region and the electrodes may be configured in an arrangement where one of the electrodes is the measuring or active electrode and the second electrode is the reference or ground electrode. In a second option for a two or more electrode configuration, when the surgical device is used with at least one of a dilator and a sheath, the reference or ground electrode may be located at a distal region of at least one of the dilator and the sheath and the active electrode located about the distal region of the surgical device.

[0013] The energy delivery device may comprise a functional tip with at least one active electrode. Further the energy delivery device may comprise a functional tip having two or more electrodes and the electrodes may be configured in an arrangement where at least one of the electrodes is active and at least one is a return electrode.

[0014] In accordance with a further aspect of the invention, there is provided a method of surgery. The method comprises: (i) introducing a surgical device into a body of a

patient, the surgical device comprising an elongate member having a distal region and a proximal region, an energy delivery device proximate to the distal region capable of cutting material and an ECG monitoring mechanism for measuring ECG proximate to the distal region; (ii) positioning the energy delivery device to a first desired location in the patient's body adjacent material to be cut using ECG signal monitoring as a guide; (iii) delivering energy using the energy delivery device to cut said material; and (iv) monitoring ECG in the heart using the ECG monitoring mechanism in order to determine the position of the surgical device. Steps (ii) and (iv) may be repeated, monitoring the ECG while positioning the device at a number of candidate locations in heart and locating the first desired location in the heart by the characteristic change in the ECG signal as the surgical device is moved against the first desired location.

[0015] The method may further comprise a step of (v) advancing the device to a second desired location. The method may comprise a step of: (vi) monitoring ECG using the ECG monitoring mechanism at the second location.

[0016] As a feature of this method aspect, step (i) comprises introducing the device into the patient's vasculature. The step of introducing the device into the patient's vasculature may comprise inserting the device into a dilator and a guiding sheath positioned in the patient's vasculature. The method may further comprise a step of (v) advancing the dilator and the sheath into the second location together over the spatially fixed surgical device or (v) advancing the dilator, sheath and surgical device all together into the second location.

[0017] In accordance with the method, the material may be tissue located on an atrial septum of a heart. Further, the region of tissue to be located using the ECG signals may be the fossa ovalis of a heart. In such a case, the ECG measured at the second location is the ECG measurement in the left atrium.

[0018] In another aspect of the invention, there is provided an electrosurgical device. The electrosurgical device comprises an elongate member having a distal region and a proximal region, said distal region insertable within and along a lumen within a body of a patient and maneuverable therethrough to a desired location where the device is operated to cut material and monitor ECG at the desired location; at least one electrode associated with the distal region for cutting tissue, said at least one electrode adapted for coupling to an electrical power source; and an ECG monitoring mechanism associated with the distal region for monitoring ECG to locate the desired location within the body, said mechanism adapted for coupling to an ECG recording system or electrocardiograph.

[0019] In a further aspect, there is provided a surgical device comprising means for cutting material at a desired location in a body of a patient; and means for determining a position of the device responsive to ECG signal change within the heart.

[0020] As a feature of this aspect, the device comprises a flexible elongate member having a proximal region and a distal region, the distal region is adapted for insertion within and along a lumen within the body and maneuverable therethrough to the desired location and the means for determining a position of the device is operable to determine the position of the distal region.

[0021] In accordance with yet another feature there is provided a method of cutting tissue at a desired location in a body of a patient. The method comprises: inserting a surgical device into the body, said surgical device comprising means for cutting material and means for determining a position of the device responsive to ECG signal change within the heart; and positioning said surgical device at the desired location in response to the means for determining a position of the device.

[0022] The method may comprise cutting material at the desired location and further comprise advancing the device in the body in response to said means for determining a position of the device. Optionally, the method comprises re-positioning said device for re-cutting in response to said means for determining a position of the device.

[0023] It is to be understood that references to cut or cutting material such as tissue in relation to the present invention may be defined as perforating, ablating, coagulating and any other mechanism to create a void.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] In order that the invention may be readily understood, embodiments of the invention are illustrated by way of examples in the accompanying drawings, in which:

[0025] **FIG. 1** illustrates a schematic view of an electrosurgical system including an electrosurgical device in accordance with an embodiment of the invention;

[0026] **FIG. 2** illustrates a side cross-sectional view of the device of **FIG. 1**;

[0027] **FIG. 3** illustrates a cross-sectional view of an alternate embodiment of the device;

[0028] **FIG. 4** illustrates an active electrode of the device of **FIG. 1**;

[0029] **FIG. 5** illustrates an alternate embodiment of the distal region of a device in accordance with the invention;

[0030] **FIG. 6** illustrates a side cross-sectional view of an alternate embodiment of the device;

[0031] **FIGS. 7A and 7B** illustrate a side view of a guiding sheath and a dilator respectively;

[0032] **FIG. 8** illustrates the position of the device of **FIG. 1** against an atrial septum of a heart; and

[0033] **FIGS. 9A and 9B** illustrate a flow chart of operation of a transseptal perforation method in accordance with an embodiment of the invention.

[0034] It will be noted that throughout the appended drawings, like features are identified by like reference numerals.

DETAILED DESCRIPTION OF THE INVENTION

[0035] **FIG. 1** illustrates an embodiment of an electrosurgical perforation device **102** in accordance with the invention in an electrosurgical system **100**. Device **102** comprises an elongate member **104** having a distal region **106**, and a proximal region **108**. Distal region **106** is adapted to be inserted within and along a lumen of a body of a patient,

such as a patient's vasculature, and maneuverable therethrough to a desired location proximate to material such as tissue to be cut.

[0036] The elongate member **104** is typically tubular in configuration, having at least one lumen **200** extending from proximal region **108** to distal region **106**. Elongate member **104** is preferably constructed of a biocompatible polymer material that provides column strength to device **102**. The elongate member **104** is sufficiently stiff to permit a dilator **710** and a soft guiding sheath **700** to be easily advanced over device **102** and through a perforation. Examples of suitable materials for the tubular portion of elongate member **104** are polyetheretherketone (PEEK), and polyimide. In a preferred embodiment, the outer diameter of the tubular portion of elongate member **104** tapers down to connect to distal region **106**. In alternate embodiments the outer diameter of elongate member **104** and the outer diameter of distal region **106** are the same.

[0037] Distal region **106** is constructed of a softer polymer material so that it is pliable and atraumatic when advanced through vasculature. An example of a suitable plastic is Pebax (a registered trademark of Atofina Chemicals, Inc.). Distal region **106** preferably has a smaller outer diameter than elongate member **104** so that dilation of a perforation is limited while the distal region **106** is advanced through the perforation. Limiting dilation ensures that the perforation will not cause hemodynamic instability once device **102** is removed. The outer diameter of distal region **106** will preferably be no larger than 0.035" (0.897 mm). This is comparable to the distal outer diameter of the transseptal needle that is traditionally used for creating a perforation in the atrial septum. Elongate member **104** is preferably no larger than 0.050" (1.282 mm) which is also comparable to the transseptal needle dimensions.

[0038] Distal region **106** terminates at functional tip region **110** which comprises a device that functions as an energy delivery device as well as an ECG monitoring device. Functional tip region **110** comprises at least one active electrode **112** made of a conductive and radiopaque material, such as stainless steel, tungsten, platinum, or another metal. Optionally, one or more radiopaque markings (not shown) may be affixed to elongate member **104** to highlight the location of the transition from distal region **106** to elongate member **104**, or other important landmarks on device **102**. Alternately, the entire distal region **106** of device **102** may be radiopaque. This can be achieved by filling the polymer material, Pebax used to construct distal region **106** with a radiopaque filler. An example of a suitable radiopaque filler is Bismuth.

[0039] Proximal region **108** comprises a hub **114**, a catheter connector cable **116**, and a connector **118**. As is known to persons of skill in the art, proximal region **108** may also have one or more depth markings **113** to indicate distances from functional tip region **110**, or other important landmarks on device **102**. Catheter connector cable **116** connects to ECG interface unit **120** via connector **118**. ECG connector cable **122** connects ECG interface unit **120** to ECG recorder **126** which displays and captures ECG signals as a function of time. Generator connector cable **126** connects ECG interface unit **120** to an energy source such as Generator **128**. ECG interface unit **120** functions as a splitter, permitting connection of electrosurgical device **102** to both ECG recorder **126** and RF generator **128**. ECG signals can be continuously monitored and recorded and the filtering circuit (not shown) within ECG interface unit **120** permits RF energy to be delivered from RF generator **128** through electrosurgical device **102** without compromising the ECG recorder **126**.

[0040] In an alternate embodiment (not shown), functional tip region **110** may comprise 2 or more active electrodes such as active electrode **112**, where one active electrode is reserved for only energy delivery and one active electrode is reserved only for ECG monitoring. In such a design ECG interface unit **120** may not be required as there are two separate circuits in the electrosurgical device: one for carrying the RF energy and the other for ECG signals.

[0041] Generator **128** is preferably a radiofrequency (RF) electrical generator that is designed to work in a high impedance range. Because of the small size of active electrode **112** the impedance encountered during RF energy application is very high. General electrosurgical generators are typically not designed to deliver energy in these impedance ranges and thus not all RF generators can be used effectively with this device. Energy is preferably delivered as a continuous wave at a frequency between about 400 kHz and about 550 kHz. An appropriate commercially available generator for this application is the BMC RF Perforation Generator (model number RFP-100, Baylis Medical Company, Montreal, Canada). This generator delivers continuous RF energy at about 460 kHz. A grounding pad **130** is coupled to generator **128** for attaching to a patient to provide a return path for the RF energy when generator **128** is operating in a monopolar mode. Other embodiments could use pulsed or non-continuous RF energy. In still other embodiments of the electrosurgical perforation device **102**, different energy sources may be used, such as microwave, ultrasound, and laser with appropriate energy delivery coupling devices and energy delivery devices.

[0042] Referring to **FIG. 2 a** cross-section of device **102** is illustrated in accordance with the embodiment of **FIG. 1**. Functional tip region **110** comprises an active electrode **112** that is coupled to an insulated conducting wire **202**. Conducting wire **202** is preferably attached to distal region **106** using an adhesive. Alternately, distal region **106** is melted onto insulation **204** on conducting wire **202** to form a bond.

[0043] Conducting wire **202** carries electrical energy from generator **128** to the active electrode **112**. Conducting wire **202** also carries action potentials or voltage measured by active electrode **112** to ECG recorder **126**. Action potentials or voltage measured by active electrode **112** is with reference to a zero potential or ground electrode (not shown) within ECG recorder **126** or a ground electrode (not shown) attached to a patient (not shown). Conducting wire **202** is covered with electrical insulation **204** made of a biocompatible material that is able to withstand high temperatures such as polytetrafluoroethylene (PTFE), or other insulating material. Conducting wire **202** preferably extends through a main lumen **200** of device **102** which lumen extends from proximal region **108** to distal region **106**.

[0044] In an alternate embodiment shown in cross section view in **FIG. 3**, an elongate member **300** comprises main lumen **302** and a separate lumen **304**. The separate lumen **304** contains a conducting wire **306** covered with electrical insulation **308** therein and main lumen **302** can be used, for

example, for aspiration of blood, injection of contrast or other media, among other purposes. Optionally, main lumen **302** which extends between proximal and distal regions of elongate member **300** provides a pressure sensing mechanism to be used for monitoring blood pressure. As is known to persons of skill in the art, main lumen **302** may be coupled to a pressure transducer, preferably external to device **102**, to produce a signal that varies as a function of pressure sensed as the surgical device is positioned in and about a body. The pressure transducer may be electrically coupled to a pressure monitoring system (not shown) that converts the transducer's signal and displays a pressure contour as a function of time. Pressure monitoring may be useful in locating a surgical device within a body.

[**0045**] In the embodiment of **FIG. 2**, main lumen **200** extends from proximal region **108** along elongate member **104** and through distal region **106** of device **102**.

[**0046**] At proximal region **108**, conducting wire **202** is electrically coupled to catheter connector cable **116** within hub **114** by an electrical joint **206**. This joint can be made by soldering, or another wire joining method known to people of ordinary skill in the art. Catheter connector cable **116** terminates with a connector **118** that can mate with either the ECG interface unit **120**, or a separate extension connector cable (not shown). Catheter Connector cable **116** and connector **118** are made of materials suitable for sterilization, and will insulate the user from energy traveling through the conductor.

[**0047**] A hub **114** surrounds electrical joint **206** and proximal end of elongate member **104** in order to conceal these connections. The hub **114** is made of a polymeric material, and is filled with a filling agent **208** such as an epoxy, or another polymeric material in order to hold catheter connector cable **116** in place.

[**0048**] Referring to **FIG. 4** there is illustrated a side cross-sectional view of a preferred embodiment of functional tip region **110**. Functional tip region **110** comprises one active electrode **112** configured in a bullet shape. Active electrode **112** is preferably 0.059" (0.15 cm) long and preferably has an outer diameter of 0.016" (0.04 cm). Active electrode **112** is coupled to an end of conducting wire **202**, also made out of a conductive and radiopaque material. RF energy is delivered through active electrode **112** to tissue, and travels through the patient to grounding pad **130**, which is connected to generator **128**. Additionally, action potentials or voltage measured from tissue through active electrode **112** travel through conducting wire **202** to ECG recorder **126**. Alternate embodiments of active electrode **112** are configured in shapes other than a bullet. These shapes include a spherical shape, a rounded shape, a ring shape, a semi-annular shape, an ellipsoid shape, an arrowhead shape, a spring shape, and a cylindrical shape, among others.

[**0049**] Referring to **FIG. 5** there is illustrated an alternate embodiment of a functional tip region **500**. Functional tip region **500** comprises one active electrode **502** in a ring configuration. Conducting wire **504** covered with electrical insulation **506** is coupled to the active electrode **502**, and active electrode **502** is positioned around a perimeter of a single opening **508** that provides a pathway between main lumen **510** and a patient's body. Another similar embodiment to functional tip region **500** comprises an active electrode in a partially annular shape (not shown). In other embodiments (not shown), a functional tip comprises multiple electrodes. Such electrodes may operate in a monopolar mode as with the embodiments detailed in **FIGS. 2 and 5**. Such electrodes may be arranged in a manner such that at least one electrode may be located distally to all the other electrodes.

[**0050**] Referring to **FIG. 6**, there is illustrated a side cross-sectional view of an alternate embodiment of device **600** which operates in a bipolar mode. Device **600** comprises an elongate member **602** having a distal region **604**, and a proximal region **606**. Elongate member **602** has at least one lumen **608** extending from proximal region **606** to distal region **604**. The outer diameter of elongate member **602** tapers down to connect to distal region **604**. In alternate embodiments the outer diameter of elongate member **602** and the outer diameter of distal region **604** are the same.

[**0051**] Distal region **604** terminates at functional tip region **610**. Functional tip region **610** comprises one active electrode **612** and one reference electrode **614**. Reference electrode **614** is located proximally to active electrode **612** on functional tip region **610**. With reference to **FIGS. 7A and 7B**, in alternate embodiments, a reference electrode **716** may be located at a distal tip **712** of a dilator **710** or a reference electrode **706** may be located at a distal tip **702** of a sheath **700**. Both the active electrode **612** and reference electrode **614** can be configured in many different shapes. These shapes include a spherical shape, a rounded shape, a ring shape, a semi-annular shape, an ellipsoid shape, an arrowhead shape, a spring shape, and a cylindrical shape, among others.

[**0052**] Proximal region **606** comprises a hub **616**, an active connector cable **618**, and a reference connector cable **620**. Both active connector cable **618** and reference connector cable **620** connect to ECG interface unit (not shown).

[**0053**] Active electrode **612** is coupled to an insulated conducting wire **622**. Conducting wire **622** carries electrical energy from a generator (not shown) to the active electrode **612**. Conducting wire **622** also carries action potentials or voltage measured by active electrode **612** to an ECG recorder (not shown). Conducting wire **622** extends through main lumen **608** of device **600**. Conducting wire **622** extends along elongate member **602** from distal region **604** to proximal region **606** and is electrically coupled to active connector cable **618** within hub **616**.

[**0054**] Reference electrode **614** is coupled to an insulated conducting wire **624**. Conducting wire **624** carries electrical energy from a patient (not shown) to a generator (not shown). Conducting wire **624** also carries action potentials or voltage measured by reference electrode **614** to an ECG recorder (not shown). Conducting wire **624** extends through main lumen **608** of device **600**. Conducting wire **624** extends along elongate member **602** from distal region **604** to proximal region **606** and is electrically coupled to reference connector cable **620** within hub **616**.

[**0055**] In the bipolar mode, RF energy is delivered through active electrode **612**, and returns to the generator through reference electrode **614**. The use of an active electrode **612** of surgical device **600** and a reference electrode **614** of device **600**, or alternatively at least one of reference electrode **706** of sheath **700** and reference electrode **716** of dilator **710**, eliminates the need for a grounding

pad to be attached to the patient as is well understood by persons of ordinary skill in the art. With an active-return electrode arrangement at or about functional tip region **610**, action potentials or voltage measured by the active electrode **612** are with reference to the ground or reference electrode **614** located at the function tip region **610** or about the tip region **610** when at least one of the reference electrode **706** of sheath **700** and reference electrode **716** of dilator **710** is used. The ECG recorder assigns a zero potential value to the reference electrode **614**, eliminating the need for a zero potential or ground electrode within the ECG recorder or on a patient. Higher fidelity recording may be achieved using a configuration with the return electrode at or about functional tip region **610**.

[**0056**] ECG recorder **122** is connected to device **102** through the ECG interface unit **120**. Hub **114** is coupled to catheter connector cable **116** that is coupled to connector **118** as shown in **FIG. 1**. Connector **118** is attached to ECG Interface unit **120**. When device **102** is maneuvered in a heart, electrical action potentials or voltage detected by active electrode **112** are transmitted along conducting wire **202** and catheter connector cable **116**, through ECG interface unit **120** and are captured and displayed on a display device (not shown) of ECG recorder **126**. Different locations in a heart are at different potentials and the voltage measured varies as the position of active electrode **122** is varied. A conversion circuit (not shown) preferably within ECG recorder **126** converts the measured voltage or potential into a picture or waveform recording that varies as a function of time.

[**0057**] Device **102** can be used for general electrosurgery in instances where it is desirable to cut tissue or other material and simultaneously monitor ECG. More specifically, it can be used for creating a perforation such as a transseptal perforation. As is known to persons of skill in the art, the frequency ranges for electrosurgery and ECG monitoring are different. Electrical filtering circuits may be used within the system to permit simultaneous delivery of RF energy and monitoring of ECG signals without electrical interference or compromise. In order to create a perforation in the heart, device **102** is delivered to the heart using a guiding sheath and dilator known to those of ordinary skill in the art. **FIGS. 7A and 7B** show embodiments of guiding sheath **700** and dilator **710**. Guiding sheath **700** has a tip **702** at the distal end and a proximal hub **704**. Optionally, guiding sheath **700** may have a reference electrode **706** located at distal tip **702**. As is known to persons of skill in the art, reference electrode **706** may be located anywhere along guiding sheath **700** and may be configured in many different shapes. Guiding sheath **700** has a lumen (not shown) through which dilator **710** is most commonly delivered. Dilator **710** has a tip **712** at the distal end and a proximal hub **714**. Optionally, dilator **710** may have a reference electrode **716** located at distal tip **712**. Dilator **710** has a lumen (not shown) through which a guidewire (not shown) or electrosurgical perforation device **102** can be delivered.

[**0058**] Referring to **FIG. 8** there is illustrated electrosurgical perforation device **102** inserted through a dilator **710** and sheath **700** within a heart **800** of a patient. Operations **900** for an embodiment of a method for creating a transseptal perforation is outlined in flow chart form in **FIGS. 9A and 9B**. In accordance with this method aspect, to deliver the tip **712** of the dilator **710** against the fossa ovalis **804** (step **902**) a guiding sheath **700** and dilator **710** with a lumen larger than the outer diameter of the electrosurgical perforation device **102** is introduced into a patient's vasculature. Access is gained to the femoral vein of the patient (not shown). Guiding sheath **700** and dilator **710**, known to those of ordinary skill in the art, are advanced together through the vasculature over a guidewire (not shown), approaching the heart from the Inferior Vena Cava **806**, into the Superior Vena Cava (SVC) **808** of the heart **800**. The guidewire (not shown) is withdrawn from the patient. The sheath **700** and dilator **710** are withdrawn from the SVC **808**, into a right atrium **810**. Contrast agent is delivered through dilator **710** while positioning the dilator **710** and sheath **700** along an atrial septum **802**. The sheath **700** and dilator **710** are now positioned within the right atrium **810** of heart **800** so that the tip **712** of dilator **710** is located against the upper region of the atrial septum **802** (step **902**).

[**0059**] Once the tip **712** of dilator **710** is in position against the upper region of the atrial septum **802**, device **102** can be advanced through the dilator **710** until functional tip region **110** is located distally to tip **712** of dilator **710** (step **904**). Device **102** is coupled to the ECG recorder **126** and an ECG signal is monitored through active electrode **112** providing an ECG tracing, known to those of ordinary skill in the art, may be shown on ECG recorder **126**. A technique for obtaining an ECG tracing was previously described. Device **102**, dilator **710**, and guiding sheath **700** are now dragged along the atrial septum **802** while monitoring the ECG tracing on the ECG recorder **126** (step **906**). Confirmation of position of active electrode **112** of device **102** against the fossa ovalis **804** is made once a distinctive change in the ECG tracing on ECG recorder **126** is observed. This is due to active electrode **112** advancing over the region of the fossa ovalis **804** which is membranous in comparison with the muscular atrial septum **802**. J. A. Alvarez et al. (1991) who performed experiments on the usefulness of the intracavitary electrocardiogram ECG (ECG recorded using a transseptal needle) in the localization of the fossa ovalis states that when the tip of the needle was laid against the fossa ovalis floor, the endoatrial electrocardiogram registered a slight or no injury curve, even when the pressure was sufficient to perforate the septum. On the contrary, the pressure on any other areas of the muscular septum or atrial walls elicited a bizarre monophasic injury curve. This shows that the ECG signal recorded by a surgical device while on the membranous fossa ovalis will be damped in comparison with the ECG signal recorded on the muscular areas of the atrial septum or atrial walls. This difference in ECG signal may be useful in locating the region of the fossa ovalis as a surgical device is positioned within a heart. ECG may be observed on a screen (not shown) and printed on a chart (not shown) for example. The distinctive change may be signaled for observation as well using an alarm such as a sound or light signal.

[**0060**] Functional tip region **110** is now directed toward the fossa ovalis **804**, a first desired location on the atrial septum **802** to create a perforation (**FIG. 8** and step **907** of **FIG. 9A**).

[**0061**] The position of functional tip region **110** and active electrode **112** may be additionally confirmed using an imaging modality such as fluoroscopy or intracardiac echocardiography. The position is evaluated and if the desired position is not confirmed (step **908**, No branch), step **906**

may be repeated. If confirmed (step **908**, Yes branch), energy may be delivered to create the perforation. For example, generator **128** is activated and RF energy is delivered through device **102** to make a perforation (step **910**).

[**0062**] The functional tip region **110** of device **102** is thereafter advanced through the perforation and into a second location (step **912**). Advancement may be monitored under fluoroscopy, for example, using the radiopaque markings (not shown) on the distal region **106** of device **102**. The preferred second location is left atrium **812** of the heart. The distal region **106** of device **102** is advanced incrementally into the left atrium **812** through dilator **704**, for example, in 1 cm (about 0.39") increments. When the distal region **106** of device **102** is believed to be located in the left atrium **812**, the evaluation of the ECG tracing (step **914**) can be performed for confirmation. Device **102** remains coupled to ECG recorder **126** so that an ECG tracing at the second location can be monitored.

[**0063**] After successful perforation, a left atrial ECG tracing, known to those of ordinary skill in the art, will be shown on the ECG' recorder **126**. In the event that the imaging and ECG tracings show that the perforation is made in an undesirable location (step **915**, No branch), device **102** is retracted into the right atrium **810** (step **916**) and is repositioned for another perforation attempt (step **906**). If the perforation is successfully made in the correct location (step **915**, Yes branch), distal region **106** of device **102** is preferably further advanced through the perforation. When device **102** is fully inserted into the dilator **710**, hub **114** of the device **102** will be flush against proximal hub **714** of dilator **710** (step **918**, **FIG. 9B**). When fully inserted, device **102** provides sufficient support to permit the dilator **710** to be advanced over it through the perforation.

[**0064**] Hub **114** of device **102** may be fixed in place spatially, and both the proximal hub **714** of dilator **710** and proximal hub **704** of sheath **700** are incrementally advanced, together, thus sliding the dilator **710** and sheath **700** over device **102** (step **920**). The tip **712** of dilator **710** and the tip **702** of sheath **700** may be monitored under fluoroscopy as they are advanced over device **102** and once the tip **712** of dilator **710** has breeched the perforation, and advanced into the left atrium **812**, the tip **702** of sheath **700** is advanced over dilator **710**, across the perforation and into the left atrium **812** (step **922**).

[**0065**] In an alternate method of advancing the sheath and dilator into the left atrium, (not shown), once distal region **106** is fully advanced through the perforation and into the left atrium **812**, and hub **114** of device **102** is flush against proximal hub **714** of dilator **710**, hub **114** of device **102** and proximal hub **714** of dilator **710** and proximal hub **702** of sheath **700** may all be advanced together. Advancement may be performed under monitoring by fluoroscopy. Forward momentum will cause the tip **712** of dilator **710** to breech the perforation, advancing into the left atrium **812**. The tip **702** of sheath **700** will follow over dilator **710**, across the perforation and into the left atrium **812**.

[**0066**] At step **924**, the positions of distal region **106** of device **102**, tip **712** of dilator **710** and tip **702** of sheath **700** are confirmed, for example, under fluoroscopy to be in the left atrium **812**. If not in the desired location (step **926**), step **920** may be repeated. If the positions are confirmed (step **926**), device **102** and dilator **710** may now be respectively withdrawn outside the body, preferably under fluoroscopic guidance (step **928**). While maintaining the position of tip **712** of dilator **710** and tip **702** of sheath **700** in the left atrium **812**, device **102** may be withdrawn. Dilator **710** may now be withdrawn outside the body under fluoroscopic guidance, while maintaining the position of the tip **702** of sheath **700** in the left atrium **812**. Optionally, a contrast agent may now be injected through sheath **700** into the left atrium **812**, or blood aspirated through sheath **700** from the left atrium **812** and sheath **700** may now be used to deliver other catheters (not shown) to the left atrium **812**.

[**0067**] The present invention in various aspects thus provides a device and method that is capable of creating a controlled perforation while determining a position of the device in response to action potentials or measured voltage at a location in the heart. In addition, the present invention provides a method for delivering a dilator and sheath over the device after the perforation. The controlled perforation is created by the application of energy by a generator to a functional tip on the device. A method for determining the position of the device may comprise monitoring action potentials or measured voltage through an active electrode in a unipolar or bipolar manner and displaying the ECG tracings on an ECG recorder. In this embodiment there is at least one active electrode at the functional tip region for monitoring action potentials which are captured and displayed as ECG tracings on an ECG recorder.

[**0068**] The device of the invention is useful as a substitute for a traditional transseptal needle to create a transseptal perforation. The device of the present invention preferably has a soft distal region with a functional tip that uses RF energy to create a perforation across a septum, making the procedure more easily controlled and less operator dependent than a transseptal needle procedure. The soft distal region of the device reduces incidents of vascular trauma as the device is advanced through the vasculature. The application of RF energy is controlled via an electric generator, eliminating the need for the operator to subjectively manage the amount of force necessary to cross the septum with a traditional needle. The present invention eliminates the danger of applying too much mechanical force and injuring the posterior wall of the heart.

[**0069**] The present invention also provides a method for the creation of a perforation in an atrial septum. ECG monitoring is particularly advantageous in this procedure, as there is the possibility of inadvertently perforating the aorta due to its proximity to the atrial septum. Electrical action potential or voltage measurements displayed as ECG tracings allow the operator to confirm that the distal end of the device has entered the left atrium, and not the aorta, or another undesirable location in the heart. Preferably, the device will also be visible using standard imaging techniques; however the ability to monitor ECG provides the operator with a level of safety and confidence that would not exist using only standard imaging techniques.

[**0070**] The present invention also provides a method for delivering the dilator and sheath over the electrosurgical perforation device into the left atrium once a successful perforation has been created. One of the main reasons for creating a transseptal perforation is to gain access to the left side of the heart for delivery of catheters or devices to treat left-sided heart arrhythmias or defects.

[0071] While the surgical device thus described is capable of cutting living tissue, it will be understood by persons of ordinary skill in the art that an appropriate device in accordance with the invention will be capable of cutting or removing material such as plaque or thrombotic occlusions from diseased vessels as well.

[0072] Although the above description relates to specific embodiments as presently contemplated by the inventors, it is understood that the invention in its broad aspect includes mechanical and functional equivalents of the elements described herein.

What is claimed is:

1. A surgical device for cutting material and monitoring ECG comprising:

an elongate member having a distal region and a proximal region;

an energy delivery device associated with the elongate member at the distal region for delivering cutting energy to the material, said energy delivery device adapted for connection to an energy source; and

an ECG monitoring device associated with the distal region for monitoring ECG, said ECG monitoring mechanism adapted for connection to an ECG recording device.

2. The device as claimed in claim 1 wherein the energy delivery device is configured to deliver at least one form of cutting energy selected from a group consisting of: electrical energy; microwave energy; ultrasound energy; and

laser energy.

3. The device as claimed in claim 1 wherein the energy delivery device is configured to deliver electrical energy comprising electrical current having a frequency within the radio frequency range.

4. The device as claimed in claim 1 wherein the material comprises cellular tissue and wherein the energy delivery device is operable to deliver sufficient energy to the tissue to result in a rapid increase in the intracellular temperature causing vaporization of intracellular water and subsequent cell lysis.

5. The device as claimed in claim 1 wherein the ECG monitoring mechanism comprises at least one active electrode about the distal region adapted for connection to an ECG recording device.

6. The device as claimed in claim 5 wherein the ECG monitoring mechanism operates in a unipolar mode.

7. The device as claimed in claim 5 wherein the distal region comprises two or more electrodes about the distal region adapted for connection to an ECG recording device; and wherein the electrodes are configured in an arrangement where at least one of the electrodes is active and at least one is a reference electrode.

8. The device as claimed in claim 7 wherein the at least one active electrode is located distally to the at least one reference electrode about the distal region.

9. The device as claimed in claim 5 wherein the surgical device is insertable into a patient's vasculature using at least one of a guiding sheath and a dilator; and wherein at least one reference electrode is located on a distal region of at least one of the sheath and the dilator.

10. The device as claimed in claim 7 wherein the ECG monitoring mechanism operates in a bipolar mode.

11. The device as claimed in claim 1 wherein the energy delivery device comprises a functional tip with at least one active electrode.

12. The device as claimed in claim 1 wherein the energy delivery device comprises a functional tip having two or more electrodes; and wherein the electrodes are configured in an arrangement where at least one of the electrodes is active and at least one is a return electrode.

13. The device as claimed in claim 1 wherein the energy delivery device and the ECG monitoring device comprise one active electrode.

14. The device as claimed in claim 1 wherein a pressure sensing mechanism is associated with the distal region for monitoring pressure about the distal region.

15. The device as claimed in claim 1 wherein the pressure sensing mechanism comprises a pressure transmitting lumen extending between the proximal and distal regions, said lumen at the proximal region being adapted for fluid communication with a pressure transducer that provides a signal which varies as a function of pressure and adapted at the distal region for fluid communication with an environment about said distal region.

16. A method of surgery comprising the steps of:

(i) introducing a surgical device into a heart of a patient, the surgical device comprising an elongate member having a distal region and a proximal region, an energy delivery device proximate to the distal region capable of cutting material and an ECG monitoring mechanism for determining ECG in the heart proximate to the distal region;

(ii) positioning the energy delivery device to a first desired location in the heart adjacent material to be cut;

(iii) delivering energy using the energy delivery device to cut said material; and

(iv) monitoring ECG in the heart using the ECG monitoring mechanism in order to determine the position of the surgical device at least one of before and after step (iii).

17. The method as claimed in claim 16 further comprising a step of:

(v) advancing the device to a second location.

18. The method as claimed in claim 17 further comprising a step of:

(vi) monitoring ECG using the ECG monitoring mechanism at the second location.

19. The method as claimed in claim 16 wherein step (i) comprises introducing the device into the patient's vasculature.

20. The method as claimed in claim 19 wherein the step of introducing the device into the patient's vasculature comprises inserting the device into a dilator and a guiding sheath positioned in the patient's vasculature.

21. The method as claimed in claim 20 comprising a step of:

(v) advancing the dilator and the sheath to a second location together over the surgical device.

22. The method as claimed in claim 20 comprising a step of:

(v) advancing the dilator, sheath and surgical device all together into a second location.

23. The method as claimed in claim 16 wherein the material is tissue located on an atrial septum of the heart.

24. The method as claimed in claim 18 wherein the ECG monitored at the second location is the ECG in the left atrium.

25. The method as claimed in claim 16 wherein step (ii) comprises dragging the surgical device about a surface of the heart while simultaneously monitoring ECG to determine the first desired location.

26. The method as claimed in claim 25 wherein the first desired location is determined in response to the observation of a distinctive change in the ECG signal.

27. The method as claimed in claim 26 wherein the ECG signal at the first desired location is damped in comparison with the ECG signal monitored otherwise on the surface of the heart as the surgical device is located about the first desired location.

28. The method as claimed in claim 26 wherein the first desired location is a fossa ovalis of the heart.

29. An electrosurgical device comprising:

an elongate member having a distal region and a proximal region, said distal region insertable within and along a lumen within a body of a patient and maneuverable therethrough to a desired location where the device is operated to cut material and monitor ECG at the desired location;

at least one electrode associated with the distal region for cutting tissue, said at least one electrode adapted for coupling to an electrical power source; and

an ECG monitoring mechanism associated with the distal region for monitoring ECG at the desired location within the body, said mechanism adapted for coupling to an ECG recording device.

30. The device as claimed in claim 29 wherein the at least one electrode defines a functional tip comprising a conductive and radiopaque material at said distal region.

31. The device as claimed in claim 30 wherein the electrical power source is capable of providing a high-frequency electrical power to said functional tip in a high impedance range.

32. The device as claimed in claim 29 wherein the proximal region is adapted to releasably couple said electrode to said electrical power source.

33. The device as claimed in claim 29 wherein the proximal region is adapted to releasably couple said electrode to said ECG recording device.

34. A surgical device comprising:

means for cutting material at a desired location in a body of a patient; and

means for determining a position of the device responsive to ECG within the heart.

35. The device as claimed in claim 34 comprising a flexible elongate member having a proximal region and a distal region, said distal region adapted for insertion within and along a lumen within the body and maneuverable therethrough to the desired location; and wherein said means for determining a position of the device is associated with the distal region to determine the position of the distal region.

36. A method of cutting tissue at a desired location in a body of a patient comprising the steps of:

inserting a surgical device into the body, said surgical device comprising means for cutting material and means for determining a position of the device responsive to ECG within the heart; and

positioning said surgical device at the desired location in response to the means for determining a position of the device.

37. The method as claimed in claim 36 comprising the step of:

cutting material at the desired location.

38. The method as claimed in claim 37 comprising the step of:

moving said device in the body in response to said means for determining a position of the device.

39. The method as claimed in claim 38 comprising re-positioning said device for re-cutting in response to said means for determining a position of the device.

* * * * *

专利名称(译)	具有心电图（ECG）监测能力的手术穿孔装置和使用ECG定位手术穿孔装置的方法		
公开(公告)号	US20050159738A1	公开(公告)日	2005-07-21
申请号	US10/760479	申请日	2004-01-21
[标]申请(专利权)人(译)	VISRAM NAHEED SHAH克尚		
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发明人	VISRAM, NAHEED SHAH, KRISHAN		
IPC分类号	A61B18/14 A61B19/00 A61B18/18		
CPC分类号	A61B18/1492 A61B2018/00351 A61B2018/00601 A61B2218/002 A61B2018/00839 A61B2019/464 A61B2018/00702 A61B2090/064		
其他公开文献	US7270662		
外部链接	Espacenet USPTO		

摘要(译)

本发明描述了一种具有功能性尖端的装置，该功能性尖端包含至少一个能够通过施加能量（例如射频（RF））在身体组织中产生受控穿孔的有源电极。可响应于在尖端处测量的ECG确定装置尖端的位置，并由连接到装置的监视器确定。该装置可用于以受控方式在身体的任何位置移除或穿透不需要的组织，特别是在房间隔中用于受控的经中隔穿刺。在该应用中，将装置引入右心房，然后将功能性尖端定位在心房隔膜上。心电图用于定位房间隔上的卵圆窝区域。施加能量以产生穿孔并监测ECG以确定穿孔是否在期望位置产生。